UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF LOUISIANA

ALEXANDRIA DIVISION

INDEPENDENT TURTLE FARMERS OF LOUISIANA, INC. — **CIVIL ACTION NO. 1:07-cv-00856**

-vs- — **JUDGE DRELL**

UNITED STATES OF AMERICA, et al. — **MAGISTRATE JUDGE KIRK**

RULING

Presently before the Court are four motions, two filed by the Plaintiff, and two filed by the Defendants. For the reasons below, the Court's disposition as to each of these motions will be as follows:

(1) the Plaintiff's Motion to Supplement the Administrative Record (Doc. 45) will be GRANTED IN PART AND DENIED IN PART;

(2) the Defendants' Motion to Supplement the Administrative Record (Doc. 46) will be GRANTED;

(3) the Plaintiff's Motion for Summary Judgment (Doc. 58) will be GRANTED IN PART AND DENIED IN PART; and

(4) the Defendants' Motion for Summary Judgment (Doc. 60) will be GRANTED IN PART AND DENIED IN PART.

Disposition will follow by a separate judgment.

I. Background

This case is, in essence, a dispute over the validity of a thirty-five-year-old ban on the sale of baby turtles. Upon closer examination, this lawsuit brings the Court to

an intersection between ongoing developments in the legal, scientific, and regulatory fields, each of which is an ever-changing area. The Plaintiff, Independent Turtle Farmers of Louisiana, Inc. ("ITFL"), is an association of commercial turtle farmers seeking to lift or amend the ban. Named as defendants in the case are the United States of America, the United States Department of Health and Human Services ("DHHS"), and the United States Food and Drug Administration ("FDA").

In 1975, the FDA enacted a ban on the sale of viable turtle eggs and live turtles with a carapace (shell) of less than four inches in length ("Turtle Ban"). 21 C.F.R. § 1240.62 (Appendix A to this ruling). The text of the FDA regulation at issue states that, "[e]xcept as otherwise provided in this section, viable turtle eggs and live turtles with a carapace length of less than 4 inches shall not be sold, held for sale, or offered for any other type of commercial or public distribution." Id. § 1240.62(b). The four limited exceptions referenced in the Turtle ban include sales "for bona fide scientific, educational, or exhibitional purposes, other than use as pets," non-commercial sales, export-only sales, or sales of marine turtles excluded from the definition of "turtles." See id. § 1240.62(e). Finally, the regulation provides that the Commissioner

> either on his own initiative or on behalf of any interested person who has submitted a petition, may publish a proposal to amend this regulation. Any such petition shall include an adequate factual basis to support the petition, and will be published for comment if it contains reasonable grounds for the proposed regulation.

Id. § 1240.62(e). The Turtle Ban remains the only federally-enacted ban on the sale of any pet.

The Turtle Ban was enacted primarily to curb the spread of salmonellosis, a condition associated with exposure to bacteria called *Salmonella*. In the preamble to the regulation, the FDA stated that "[c]hildren are particularly susceptible to salmonellosis, tend to have more severe cases than adults, and are subject to infection transmitted when playing with pet turtles." 40 Fed. Reg. at 22543 (May 23, 1975).[1] Furthermore, the FDA relied upon studies which indicated that as much as fourteen percent of salmonellosis cases in the United States (or 280,000 of approximately 2,000,000 cases annually) were "turtle-related." See id. As a result, the FDA concluded that "a total ban with the exceptions provided by § 1240.62(d) is the only effective method *at the present time* [in 1975] that will eliminate the possibility of human illness due to contaminated turtles." Id. (emphasis added). It is arguable that the Turtle Ban accomplished at least its immediate goal. One 1980 study cited by the Defendants indicated that the FDA ban on interstate shipment of pet turtles, combined with state certification laws, had significantly reduced turtle-related salmonellosis cases in the United States. (Doc. 60-5, Exh. B).[2]

In the intervening decades since the enactment of the Turtle Ban, scientific advances and societal changes have obviously taken place. For instance, as the ITFL points out, liquid antibacterial hand soap has become a common item. More

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[1] The FDA also stated that "small children, for whom most pet turtles are purchased, cannot be expected to understand the reasons for, or abide by, sanitary measures that might protect them from illness." 40 Fed. Reg. at 22543.

[2] According to the study, "data suggests an annual decrease of 100,000 cases [of salmonellosis] among children aged 1 to 9 years." (Doc. 60-5, Exh. B, Bates No. 2805). Notably, the study pointed out that the reduction in salmonellosis cases likely resulted from a decrease in the number of turtles sold, and not from the production of turtles certified as *Salmonella*-free.

relevantly, however, researchers have undertaken various scientific efforts to reduce the incidence of *Salmonella* in baby turtles. The ITFL cites studies conducted by university professors, and submitted to the FDA, demonstrating that certain treatment methodologies can reduce or eliminate *Salmonella* from the eggs and hatchlings of red-eared slider ("RES") turtles.[3] Nonetheless, the FDA maintains that the Turtle Ban has sharply reduced reducing turtle-related salmonellosis cases. According to the FDA, further research is needed to show that turtles can be produced free of *Salmonella*, without resistance to treatments, and without a risk of future *Salmonella* re-colonization.

Because of these concerns, the Turtle Ban has remained in effect for almost thirty-five years. Nearly four years ago, the ITFL decided to challenge the Turtle Ban. Pursuant to 21 C.F.R. § 1240.62, the ITFL presented a petition dated April 10, 2006 to the FDA, along with a lengthy volume of attachments, seeking to lift or amend the Turtle Ban. Included were two affidavits, one from the Louisiana Commissioner of Agriculture and Forestry, and the other from Mark Mitchell ("Dr. Mitchell"), a veterinarian and professor at Louisiana State University. Both affidavits concluded that the sale of baby turtles as pets posed no greater risk of causing salmonellosis than the sale of other pets. (Doc. 58-3, Exh. 11). In a separate letter submitted to the FDA, Dr. Mitchell also maintained that research conducted on the use of non-antibiotic compounds to control the incidence of *Salmonella* contamination in RES turtles concluded that "*Salmonella* was significantly reduced or eliminated in water,

[3] These studies will be discussed in more detail as they become relevant.

eggs or hatchlings." (Doc. 58-4, Exh. 12). Finally, Dr. Mitchell opined that the Turtle Ban is patently unfair because the FDA guidelines covering the "poultry, beef, swine, vegetables, and fruit" industries are less stringent, because *Salmonella* "cannot be completely controlled" in those products. (Doc. 58-4, Exh. 12).

In a letter dated May 31, 2006, the FDA denied the ITFL's petition to lift the Turtle Ban. Specifically, the FDA concluded that the ITFL's "submission . . . does not demonstrate that *Salmonella*-free turtles can be consistently produced and that, if *Salmonella*-free turtles are produced, they will not be recontaminated with *Salmonella sp.* after shipment." (Doc. 58-4, Exh. 18). The FDA distinguished between the pet turtle industry and the food industry by noting that the "at-risk population" protected by the Turtle Ban consists of small children.

Following the FDA's decision, the ITFL filed this lawsuit on May 18, 2007, seeking a judgment from the Court: (1) declaring that the Turtle Ban exceeds the FDA's statutory authority; (2) declaring that continued enforcement of the Turtle Ban is arbitrary and capricious under the Administrative Procedure Act, 5 U.S.C. §706(3)(a), (c); (3) declaring that the ITFL's Fifth Amendment rights have been violated; (4) enjoining enforcement of the Turtle Ban; (5) awardng the ITFL costs and fees; and (6) awarding the ITFL any other relief to which it may be entitled. (Doc. 1). Subsequently, the ITFL filed a Motion for Discovery and Extra-Record Supplementation (Doc. 10), which was granted on March 27, 2008 (Doc. 24). Two motions to compel filed by the ITFL (Docs. 28, 38) were also granted by the magistrate judge (Docs. 35, 43).

On April 1, 2009, the parties each filed a motion to supplement the administrative record (Docs. 45, 46), which, according to both parties, lacked at least some documents that should have properly been included in the record when it was filed. Other documents remain in dispute, and will be discussed and delineated below. Shortly after these motions were filed, the parties submitted competing motions for summary judgment (Docs. 58, 60). These four motions remain pending. After a careful review of the record, the parties' filings, and the law applicable to the various facets of this case, the Court is now prepared to rule.

II. Law and Analysis

A. Judicial Review

A threshold question before us is whether this case may properly be reviewed at this point, given its procedural posture and its history before the administrative agency. Under the APA, "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." 5 U.S.C. § 702. The statute provides the following guidelines to determine whether agency action is reviewable:

> Agency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review. A preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action. Except as otherwise expressly required by statute, agency action otherwise final is final for the purposes of this section whether or not there has been presented or determined an application for a declaratory order, for any form of reconsideration, or, unless the agency otherwise requires by rule and provides that the action meanwhile is inoperative, for an appeal to superior agency authority.

Id. § 704. Accordingly, "[t]he APA permits 'non-statutory' judicial review only of 'final

agency action.'" Veldhoen v. U.S. Coast Guard, 35 F.3d 222, 225 (5th Cir. 1994). If no final agency action took place, the Court lacks subject matter jurisdiction to hear the dispute. See id. As a general principle, "[a] final agency action is one that imposes an obligation, denies a right, or fixes a legal relationship." Id. (citing U.S. Dep't of Justice v. Fed. Labor Relations Auth., 727 F.2d 481, 493 (5th Cir. 1984)).

In this case, the FDA's denial of the ITFL's petition constitutes final agency action. The petition was submitted in accordance with the only procedure set forth in the governing regulation by which a party may seek review of the Turtle Ban. Moreover, the FDA's response to the petition was unconditional, definitive, and at least purported to observe the requirements of the regulation.[4] FDA procedural regulations explicitly provide that a decision on a petition is final agency action: "Unless otherwise provided, the Commissioner's final decision constitutes final agency action (reviewable in the courts under 5 U.S.C. 701 *et seq.* and, where appropriate, 28 U.S.C. 2201) on a petition submitted under § 10.25(a)." 21 C.F.R. § 10.45(d). Therefore, the Court has jurisdiction to review the FDA's action.

B. Motions to Supplement the Administrative Record

The Defendants filed the administrative record with this Court on August 13, 2007. (Doc. 5). The record contains three tabs, which consist of: (1) a copy of the Federal Register containing the 1975 Turtle Ban regulation; (2) the April 10, 2006 petition filed by the ITFL, along with all of the attachments to the petition; and (3) the May 31, 2006 letter response denying the ITFL's petition. It is clear that these three

[4] That statement is a matter of some controversy in the parties' motions for summary judgment.

tabs, standing alone, do not contain the entire administrative record, as that term is defined under the APA. As such, the magistrate judge granted a motion to compel filed by the ITFL (Doc. 38), noting that "the agency must produce the basis for its determination-everything it relied on-whether it is research, a book, a scientific or medical journal or paper, or the opinion of an agency physician, scientist or other professional." (Doc. 43, pp. 3-4). We now review the admissibility of balance of the documents in dispute.

1. Legal Standards

The Court's review of the FDA's decision, as an administrative agency, is necessarily governed by narrow limitations. Avoyelles Sportsmen's League, Inc. v. Marsh, 715 F.2d 897, 905 (5th Cir. 1983). As noted above, the APA provides that "[a] person . . . aggrieved by agency action . . . is entitled to judicial review thereof." 5 U.S.C. § 702. As a general rule, however, "'the focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court.'" Woods v. Fed. Home Loan Bank Bd., 826 F.2d 1400, 1408 (5th Cir. 1987) (quoting Camp v. Pitts, 411 U.S. 138, 142 (1973)). "Agency action is to be upheld, if at all, on the basis of the record before the agency at the time it made its decision." State of La., *ex rel.* Guste v. Verity, 853 F.2d 322, 327 n.8 (5th Cir. 1988). As such, courts typically must not review evidence outside of the administrative record. See id. This principal is commonly referred to as the "record rule."

However, the record rule is not absolute. Courts routinely consider extra-record evidence in cases implicating the National Environmental Policy Act of 1969.

See Sierra Club v. Peterson, 185 F.3d 349, 369-70 (5th Cir. 1999); accord Coliseum Square Ass'n, Inc. v. Jackson, 465 F.3d 215, 247 (5th Cir. 2006) ("Extra-record evidence may be admitted if necessary to determine whether an agency has adequately considered adverse environmental impacts.").[5] Moreover, the Fifth Circuit extended its willingness to consider extra-record evidence in the National Forest Management Act context. Sierra Club, 185 F.3d at 370. In the broadest construction discovered by the Court in our circuit, eight exceptions to the record rule were articulated, which allow the Court to consider "extra-record" evidence:

> (1) the agency does not adequately explain its action in the administrative record supplied to the court; (2) the agency failed to consider factors relevant to its final decision; (3) the agency considered evidence omitted from the administrative record; (4) the case is so complex that additional evidence is needed to enable the court to clearly understand the issues; (5) evidence arising after the agency action shows whether the decision was correct or not; (6) the agency is sued for failing to take action; (7) the case arises under the National Environmental Policy Act ("NEPA"); and (8) relief is at issue, especially at the preliminary injunction stage.

Triplett v. Fed. Bureau of Prisons, No. 3:08-CV-1252-K, 2009 WL 792799, at *8 (N.D. Tex. Mar. 24, 2009) (citing ITT Fed. Servs. Corp. v. United States, 45 Fed. Cl. 174, 185 (1999)); accord City of Dallas v. Hall, Nos. 3:07-CV-0060-P, 3:07-CV-0213-P, 2007 WL

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[5] See also Davis Mountains Trans-Pecos Heritage Ass'n v. Fed. Aviation Admin., 116 F. App'x 3, 12 (5th Cir. 2004) ("This court has recognized an exception to the general rule, however, where examination of extra-record materials is necessary to determine whether an agency has adequately considered environmental impacts under NEPA."); Holy Cross v. U.S. Army Corps of Eng'rs, 455 F. Supp. 2d 532, 538 (E.D. La. 2006) ("As the Fifth Circuit has explained, 'NEPA imposes a duty on federal agencies to compile a comprehensive analysis of the potential environmental impacts of its proposed action, and review of whether the agency's analysis has satisfied this duty often requires a court to look at evidence outside the administrative record.'") (quoting Sierra Club, 185 F.3d at 370); Save Our Wetlands, Inc. v. Conner, No. Civ.A. 98-3625, 1999 WL 508365, at *1-2 (E.D. La. July 15, 1999) ("Although the Supreme Court has indicated that the record should be the 'focal point for judicial review', it has refrained from establishing an absolute record rule in all cases. Strict application of the record rule in NEPA cases undermines Congress' reasons for enacting NEPA.") (internal citations omitted).

3257188, at *5 (N.D. Tex. Oct. 29, 2007). The ITFL requests that the Court consider various pieces of extra-record evidence under exceptions (1), (2), (3), and (4).[6]

2. The ITFL's Motion to Supplement the Administrative Record

The ITFL has filed a motion to supplement the administrative record, alleging that the record is both incomplete and insufficient to support the FDA's decision. Of the forty-nine documents submitted by the ITFL as proposed supplements to the record, the Defendants oppose the admission of fourteen, on the grounds that those documents were created after the agency decision, and thus, could not have been part of the agency record.

The Defendants do not object to the Court's inclusion and consideration of: (1) emails among FDA officials discussing the ITFL's petition as part of the administrative record; (2) a letter from Dr. Mark Mitchell sent to the FDA in December 2005 as part of the administrative record; (3) newspaper articles, publications, and correspondence among FDA officials, as extra-record materials. Without objection from the Defendants, the Court will admit these documents as requested. Specifically, the first two categories of documents will be added to the administrative record. Because the Defendants contend that the third category of documents "were located in FDA's files, but were not considered or relied upon by the agency as part of its review of the petition," the Court will consider these documents as unopposed extra-record evidence. (Doc. 55, p. 8).

The remaining fourteen documents are: (1) four scientific or journalistic

[6] The ITFL does not, however, specify which of the exceptions to the record rule may apply to each of its proposed submissions.

publications that postdate the May 31, 2006 decision; (2) five letters written to the FDA after its May 31, 2006 decision; (3) the analysis of a 1987 Michigan state senate bill; (4) suggested language for the 2005 congressional appropriations bill from then-Congressman David Vitter; and (5) three letters from Nathan Sharff to the FDA written in 1995, in which Mr. Sharff references a method of producing *Salmonella*-free baby turtles. Overall, the Defendants argue that the ITFL has failed to show that these documents satisfy one of the exceptions to the record rule, and that because many of the documents were created or published after May 31, 2006, they could not have been considered by the FDA in denying the petition.

The ITFL argues broadly that the record as it stands "does not contain any science or background surrounding either the decision to ban baby turtles or the rationale to continue the ban." (Doc. 45, p. 2).[7] Furthermore, in its motion for summary judgment, the ITFL argues that all of the documents submitted to the Court should either be made part of the administrative record or judicially noticed, as all of the documents are either published documents and/or contained within the FDA's files. The Defendants are correct that the ITFL does not suggest the application of particular exceptions to each of the documents. Nonetheless, the ITFL's position may fairly be construed as a broad argument to apply the designated record rule exceptions from the eight-exception listing quoted above. See Triplett, 2009 WL 792799, at *8.

[7] Our review is not of the FDA's initial decision to implement the Turtle Ban. Instead, the Court is considering the validity of the FDA's decision to deny the ITFL's petition, which sought to lift the Turtle Ban. We note, however, that these two inquiries overlap at certain intervals.

First, as to the publications which postdate the FDA's decision, we find that factors (1), (2), and (3) support the admission of these documents as extra-record evidence. In particular, these documents serve primarily to show that "the agency d[id] not adequately explain its action in the administrative record supplied to the court." See id. The articles discuss the history and impacts of the Turtle Ban, and the risk of *Salmonella* contraction following exposure to sources other than baby turtles, including certain types of food, pets, and pet food. These publications merely buttress points that were raised by the ITFL in its petition and supporting documents, and also serve as background evidence. More importantly, some are points which the FDA largely conceded in its May 30, 2006 letter response.[8] They are cited in support of the ITFL's arguments regarding the prevalence of *Salmonella* contamination in the food and pet industries, and thus, of the possibly unreasonable nature of the FDA's denial of the petition.[9] Finally, and frankly, they add very little to the debate that was not before the FDA at the time that it made its determination. Thus, we find the publications admissible as extra-record evidence.

Second, the post-decision letters written to the FDA by ITFL supporters do not satisfy one of the exceptions to the record rule. The letters are little more than redundant, although erudite, expressions of disagreement with the FDA decision

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[8] Specifically, the FDA stated that: "[w]e recognize many other products may be contaminated with microorganisms, including *Salmonella*." (Doc. 58-4, Exh. 18, p. 1).

[9] We also note that three of the four disputed articles were published less than one year after the FDA's decision. As such, they do not contain "groundbreaking" developments which likely would have altered the FDA's determination had they been discovered before the FDA's decision. Rather, they serve to elucidate the ITFL's arguments and enlighten the Court as to the scientific foundation of those arguments.

written by ITFL representatives.[10] In part, the letters also discuss events subsequent to the FDA's denial of the petition. None of these purposes justifies a departure from the record rule. Therefore, the letters are not admitted as extra-record evidence.

Next, the Court will not consider a Michigan Senate Fiscal Agency analysis of a bill proposal which sought to close the "loophole" in the federal Turtle Ban allowing baby turtle sales for "educational purposes." (Doc. 45-4, Bates Nos. 2682-2683). The document is certainly not scientific in nature. Instead, it merely expresses the pragmatic opinion of the analyst-authors regarding a point not directly in contention in this litigation. As such, it meets none of the exceptions to the record rule. The ITFL's fourth sought supplement, a letter written by then-Congressman David Vitter containing "Requested Report Language for FY2005 Agriculture Appropriations," suffers from the same deficiency. Although then-Congressman Vitter summarized the view of the "Conferees" that the Turtle Ban was unfair, the document does not satisfy a record rule exception, and will not be admitted.

Finally, the ITFL seeks to admit two 1995 letters from Sharff Research Corporation to the FDA claiming that the company had developed a method of producing *Salmonella*-free turtles and requesting guidance as to how to present this information to the proper authorities with the FDA. These letters will not be considered as extra-record evidence, as they fail to meet one of the exceptions to the

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[10] As the Defendants point out, letters expressing disagreement with an agency decision have been rejected as extra-record evidence in other cases. See, e.g., Am. Wildlands v. Kempthorne, 530 F.3d 991, 1002 (D.C. Cir. 2008) (declining to admit as extra-record evidence letters from consulted scientists, because the letters were "not part of the administrative record," and "merely disagree with the [agency's] conclusions").

record rule. The ITFL has not articulated the value of the letters under any of the recognized exceptions. In fact, there are no further indications before the Court as to what Mr. Sharff's methods may have been, whether his claims were supportable, and whether his research impacted the ITFL's petition in any way. As a result, the letters will not be admitted as extra-record evidence.

In sum, we partially grant the ITFL's motion only as a precursor to ruling upon the issues presented by the parties in their cross-motions for summary judgment. The evidence which will be excluded by the Court's ruling will be considered in the nature of a proffer, but will not be formally added to the administrative record. Therefore, the ITFL's Motion to Supplement the Administrative Record (Doc. 45) will be GRANTED IN PART AND DENIED IN PART. The Court's disposition as to each of the proposed supplements will be specifically delineated in a separate judgment.

3. The Defendants' Motion to Supplement the Administrative Record

The Defendants seek to supplement the administrative record by adding three memoranda drafted by FDA employees and considered as part of the FDA's decision to deny the ITFL's petition. The ITFL does not oppose the inclusion of the memoranda, but "harbor concerns" as to why the documents were initially withheld, and argue that if the Defendants are allowed to supplement the administrative record, then the ITFL should be as well.

Because both parties agree that these memoranda were considered as part of the FDA's decision, supplementation of the record to include the memoranda is appropriate. While we note the ITFL's concerns, the Defendants have explained that

the memoranda were omitted from the administrative record under the deliberative process privilege. The Defendants subsequently waived that privilege and produced the memoranda to the ITFL in July 2008. Therefore, the Defendants' Motion to Supplement the Administrative Record (Doc. 46) will be GRANTED, and the three memoranda attached to the Defendants' Motion and marked as Exhibits A-C will hereby be added to the administrative record in this matter.

C. Cross-Motions for Summary Judgment

1. Summary Judgment Standard

Under Rule 56(c), the Court will grant a party's motion for summary judgment only if:

> the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law.

Fed. R. Civ. P. 56(c). A genuine issue of material fact exists if the evidence is such that a reasonable jury could return a verdict in favor of the nonmoving party. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249-50 (1986).

Where adverse parties have filed cross-motions for summary judgment, we "'review each party's motions independently, viewing the evidence and inferences in the light most favorable to the nonmoving party.'" Tidewater Inc. v. United States, 565 F.3d 299, 302 (5th Cir. 2009) (quoting Ford Motor Co. v. Tex. Dep't of Transp., 264 F.3d 493, 499 (5th Cir. 2001)). However, mere conclusory allegations are not competent summary judgment evidence, and such allegations are insufficient to defeat a motion for summary judgment. Brock v. Chevron U.S.A., Inc., 976 F.2d 969,

970 (5th Cir. 1992).

The Court also notes that the filing of cross-motions "does not necessarily constitute an agreement to trial on a stipulated record." John v. State of La. Bd. of Trs., 757 F.2d 698, 705 (5th Cir. 1985). Likewise, the fact that both parties argue there are no genuine issues of material fact does not mandate that a district court resolve the dispute without a trial. Dotson v. City of Indianola, 739 F.2d 1022, 1026 n.5 (5th Cir. 1984). However, the Fifth Circuit has noted that the summary judgment device is uniquely well-suited for disputes involving decisions made by administrative agencies, such as the FDA:

> The summary judgment procedure is particularly appropriate in cases in which the court is asked to review or enforce a decision of a federal administrative agency. The explanation for this lies in the relationship between the summary judgment standard of no genuine issue as to any material fact and the nature of judicial review of administrative decisions. . . . [T]he administrative agency is the fact finder. Judicial review has the function of determining whether the administrative action is consistent with the law-that and no more.

Girling Health Care, Inc. v. Shalala, 85 F.3d 211, 214-15 (5th Cir. 1996) (quoting 10A Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, Federal Practice and Procedure: Civil 2d § 2733 (1983)).

2. *Summary of the Arguments*

In its motion for summary judgment, the ITFL presents a progressive series of arguments: (1) *Salmonella* in baby turtles can now be eliminated by a simple treatment method; (2) the Turtle Ban, which is the only federal ban on the sale of any pet, is unnecessary to protect children from the spread of *Salmonella* in the modern world, given advances in medical science and the common use of antibacterial soap;

(3) the FDA's refusal to lift the Turtle Ban in light of these circumstances is arbitrary and capricious; and (4) the sale of pets is not within the FDA's jurisdiction to regulate, and thus, the Turtle Ban exceeds the scope of the FDA's jurisdiction.

The Defendants argue that the FDA properly derived statutory authority to enact the Turtle Ban as a means of preventing the spread of communicable diseases. Moreover, the Defendants maintain that baby turtles continue to pose a significant health hazard, and therefore, the FDA's decisions to enact and continue the Turtle Ban were not arbitrary and capricious. Because these arguments largely intersect, will consider the parties' cross motions for summary judgment in concert.

3. Arguments not Raised in the ITFL's Petition

As an initial matter, the Defendants submit that a number of the ITFL's arguments to this Court were not raised in the ITFL's petition to the FDA, and thus, cannot be relied upon at this stage. Those arguments are: (1) any challenge to the original enactment of the Turtle Ban, including (a) that it exceeded the FDA's statutory authority; (b) that the FDA cannot mandate the destruction of uncontaminated turtles; (c) that the ban on baby turtles was arbitrary and capricious because larger turtles also carry *Salmonella*; or (d) that the statute, as originally enacted, should have defined the term "reasonable grounds"; and (2) as to the FDA's May 31, 2006 denial of the ITFL's petition, (a) the FDA should have conducted its own risk assessment; (b) the FDA should have taken various "scientific advances" into account; or (c) numerous other pets also carry *Salmonella*.

Prior to seeking judicial review of an agency decision, claimants typically must

present all of the issues upon which they seek relief to the administrative agency. See Sims v. Apfel, 530 U.S. 103, 107-09 (2000). This principle is often referred to as the "issue-exhaustion" requirement. See id. at 108. The central elements of the issue-exhaustion requirement have been summarized as follows:

> [T]he [Supreme] Court [in Sims v. Apfel] began by noting that issue exhaustion requirements are usually created by statute. Alternatively, an issue exhaustion requirement may be imposed by an agency's regulations requiring a claimant to exhaust all issues in administrative appeals. Absent either a statute or regulation requiring issue exhaustion, a court may impose it where it is appropriate to do so. The Court recognized that a judicially imposed issue exhaustion requirement may be proper because it is an "analogy to the rule that appellate courts will not consider arguments not raised before trial courts." The degree to which such an analogy applies is dependent on whether the particular administrative proceeding is similar to traditional litigation-that is, whether the proceeding before the administrative agency is sufficiently "adversarial." The rationale for requiring issue exhaustion is that parties should have an opportunity to offer evidence before the administrative agency charged with the fact finding responsibility. This rationale is strongest in cases in which "the parties are expected to develop the issues in an adversarial administrative proceeding." The Court warned, however, of the "'wide differences between administrative agencies and courts.'" And the Court counseled "against reflexively 'assimilat[ing] the relation of . . . administrative bodies and the courts to the relationship between lower and upper courts.'"

Delta Found., Inc. v. United States, 303 F.3d 551, 560 (5th Cir. 2002) (internal citations omitted). When the duty to exhaust issues is statutory, rather than jurisprudential, a party's failure to first present an issue to the administrative agency deprives a court of jurisdiction over that particular issue. Omari v. Holder, 562 F.3d 314, 319 (5th Cir. 2009).[11]

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[11] Formal administrative regulations carry the force and effect of law. Demahy v. Actavis, Inc., 593 F.3d 428, 434 (5th Cir. 2010); accord Alvidres-Reyes v. Reno, 180 F.3d 199, 205 (5th Cir. 1999) (holding that immigration regulations "have the force and effect of law").

For purposes of clarity, the ITFL is seeking judicial review of the FDA's denial of its petition to amend or overturn the Turtle Ban. FDA regulations require that

> [a] request that the Commissioner take or refrain from taking any form of administrative action must first be the subject of a final administrative decision based on a petition submitted under § 10.25(a) or, where applicable, a hearing under § 16.1(b) before any legal action is filed in a court complaining of the action or failure to act.

21 C.F.R. § 10.45(b). The ITFL properly submitted its petition to the FDA before instituting this lawsuit. However, the FDA regulation governing the institution of proceedings, such as the filing of petitions, contains an explicit issue-exhaustion requirement:

> FDA has primary jurisdiction to make the initial determination on issues within its statutory mandate, and will request a court to dismiss, or to hold in abeyance its determination of or refer to the agency for administrative determination, any issue which has not previously been determined by the agency or which, if it has previously been determined, the agency concluded should be reconsidered and subject to a new administrative determination.

Id. § 10.25(b). Therefore, any substantive "issues" not at least presented to the FDA by the ITFL may not be reviewed by the Court at this juncture.

The ITFL failed to present the following issues to the FDA in its petition: (1) that larger turtles carry *Salmonella*; (2) that the Turtle Ban itself fails to define the term "reasonable grounds"; or (3) the possible impacts of "scientific advances" such as antibacterial soap and antibiotic treatments. However, it is clear from the face of the Turtle Ban that the term "reasonable grounds" is not defined in the regulation. The Court also may not ignore the fact that science has progressed since the Turtle Ban was passed, resulting in an increase in the availability of hygienic tools such as

antibacterial soap.[12] But without presentation of arguments to the FDA on these issues, we are foreclosed from evaluating them in any substantive capacity.

The issue of whether the Turtle Ban exceeds the FDA's statutory authority is properly reviewable at this stage in the litigation.[13] The Turtle Ban itself calls for submission of petitions which seek "to amend th[e] regulation." 21 C.F.R. § 1240.62 (e). To the extent that the petitioner wishes to challenge the scientific basis of the Turtle Ban, this procedure applies. However, the ITFL challenges the FDA's statutory authority under the APA, as discussed below. We are aware that, as a general principle, "the administrative agency is to determine its own jurisdiction initially." Usery v. Tamiami Trail Tours, Inc., 531 F.2d 224, 242 (5th Cir. 1976). But the agency did just that by enacting the Turtle Ban, and its judgment was affirmed by the district court in State of La. v. Mathews, 427 F. Supp. 174, 176 (E.D. La. 1977).[14] The argument is a purely legal question of statutory interpretation that was initially determined by the FDA in 1975, not a novel "issue" which the agency had no

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[12] There is no scientific evidence before the Court that larger turtles carry *Salmonella*, although the lay person could reasonably infer that they do.

[13] Also included in our analysis here is the ITFL's argument that the FDA does not have the statutory authority to destroy healthy turtles.

[14] On this point, we draw a parallel to the Fifth Circuit's reasoning in Texas v. United States relating to a ripeness challenge. See 497 F.3d 491, 499 (5th Cir. 2007). The court held that a challenge to procedures proumlgated by the Secretary of the Interior Department related to gaming regulations was ripe for judicial review, because the enactment of the procedures themselves was "final agency action." See id. We also note that "'a federal court always has jurisdiction to determine its own jurisdiction.'" M.L. v. El Paso Indep. School Dist., No. 09-50436, 2010 WL 816842, at *2 (5th Cir. Mar 9, 2010) (quoting United States v. Ruiz, 536 U.S. 622, 628 (2002)).

opportunity to consider.[15] Therefore, we will analyze whether the Turtle Ban exceeds the FDA's authority under the empowering statute.

Next, we will consider the second category of arguments challenged by the Defendants. The first argument, that the FDA should have conducted its own risk assessment, may be dealt with summarily. The argument is neither grounded in law nor in research, but is rather a general assertion that no evidence contrary to the studies submitted by the ITFL has been presented. Thus, it is not an "issue" subject to preclusion. However, the argument that the FDA should have taken scientific advances into account carries more significant weight. The ITFL's petition certainly presents no scientific evidence of what effect modern conveniences such as antibacterial hand soap may have upon the spread of *Salmonella*. At the same time, the Court does not evaluate claims in a vacuum, and thus, cannot ignore the fact that the Turtle Ban was implemented at a time when less hygienic tools were widely available to the public. But, once again, because the FDA had no opportunity to evaluate the impact of those "advances," we should not avail ourselves of the opportunity to do so at this stage.

Finally, the issue of other pets being contaminated with *Salmonella* was

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[15] Recognized exceptions to the issue-exhaustion rule include circumstances in which "the adequacy of the administrative remedy is essentially coextensive with the merits of the claim (e.g., the claimant contends that the administrative process itself is unlawful)," and in which "exhaustion of administrative remedies would be futile because the administrative agency will clearly reject the claim." Taylor v. U.S. Treasury Dep't, 127 F.3d 470, 477 (5th Cir. 1997). In this case, it is clear that a systemic challenge to the Turtle Ban, rather than a petition challenging the substance of the ban itself (as is contemplated in the regulation), likely would have failed. Similarly, an argument questioning the FDA's statutory authority to enact the Turtle Ban after decades of its existence and numerous other challenges to its viability would have shared the same fate. In short, assailing the FDA's statutory authority in this case would have been futile.

included in the administrative record. No scientific evidence to substantiate that claim was included in the petition. As a logistical (and likely widely-known) point, however, Dr. Mitchell's affidavit, which was attached to the petition, fairly raises the issue.[16] This argument is properly before the Court.

Therefore, the Court will consider the issues that were initially presented to the FDA in the ITFL's April 10, 2006 petition. The remaining issues which are barred by the issue-exhaustion requirement will be remanded to the FDA for further consideration, as detailed below.

4. In Excess of Statutory Jurisdiction

We next address the dispositive issue of whether the FDA had the authority to enact and maintain the Turtle Ban. Pursuant to the APA, a court may overturn an agency decision which is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C). Although the FDA has asserted that the Turtle Ban addresses serious health risks to citizens, including children, the limits of the FDA's jurisdiction are nonetheless preeminent. "Regardless of how serious the problem an administrative agency seeks to address . . . it may not exercise its authority 'in a manner that is inconsistent with the administrative structure that Congress enacted into law.'" Texas v. United States, 497 F.3d at 501 (quoting FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 125 (2000)). Thus, we must decide

[16] Dr. Mitchell stated: "I believe that the sale of these animals will not produce any greater health risk to humans than any other pet." (Doc. 5-3, Tab 2). Furthermore, in a December 4, 2005 letter, which has been added to the administrative record with the Defendants' consent, Dr. Mitchell specifically referred to the "Captive reptile" and "Pocket pet/small rodent" industries as ones producing "products" that may potentially carry *Salmonella*, but that are not subject to similar regulation.

whether Congress delegated the power to the FDA to regulate the sale of turtles as pets.

The principal statute empowering the FDA to regulate certain products and industries is the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq*. The Supreme Court has stated that "the [FDCA] generally requires the FDA to prevent the marketing of any drug or device where the 'potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit.'" Brown & Williamson Tobacco Corp., 529 U.S. at 134 (holding that "Congress intended to exclude tobacco products from the FDA's jurisdiction"). On face, this statute does not appear to grant the FDA the authority to regulate the sale of pets.

However, we need not decide this issue, as the Defendants maintain that the FDA derived the authority to enact the Turtle Ban from another provision. Specifically, the Defendants contend that Section 361 of the Public Health Service ("PHS") Act granted the FDA broad authority to enact measures such as the Turtle Ban:

> The Surgeon General, with the approval of the Secretary, is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary.

42 U.S.C. § 264(a) ("Section 361"). This provision is listed under the "authority" section following 21 C.F.R. § 1240.62. Moreover, in the only case evaluating the

efficacy of the Turtle Ban, the district court held that "the intrastate [Turtle Ban] is not only authorized by [42 U.S.C. § 264], but, under modern conditions of transportation and commerce is clearly reasonable to prevent the interstate spread of disease." Mathews, 427 F. Supp. at 176.[17] Like the Matthews court, we evaluate the FDA's authority to enact the provision under the PHS Act, rather than the FDCA.

First, we conclude that Section 361 applies to the FDA as an agency. Although Section 361 does not explicitly grant regulatory authority to the FDA, subsequent changes in the structure of the agencies involved, as well a delegation of authority from the Secretary of the DHHS, make clear that the FDA is empowered to issue regulations under Section 361.[18] Furthermore, turtle-related Salmonellosis was properly targeted by the FDA under its Section 361 authority to hedge against the spread of "communicable diseases." By separate regulation, the FDA defined "communicable diseases" to mean "[i]llnesses due to infectious agents or their toxic products, which may be transmitted from a reservoir to a susceptible host either

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[17] The court's decision in Matthews is, of course, not binding upon the Court.

[18] The term "Secretary" in the statute refers to the Secretary of the DHHS. 42 U.S.C. § 242q-4(2). Notes adjoining this statue explain that

> [t]he Office of the Surgeon General was abolished by section 3 of 1966 Reorg. Plan No. 3, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and all functions thereof were transferred to the Secretary of Health, Education, and Welfare [now Secretary of Health and Human Services] by section 1 of 1966 Reorg. Plan No. 3, set out under section 202 of this title. The Secretary of Health, Education, and Welfare was redesignated the Secretary of Health and Human Services by section 509(b) of Pub.L. 96-88 which is classified to section 3508(b) of Title 20, Education.

The Defendants cite to a provision in a FDA Staff Manual Guide, noting that the Secretary has delegated all powers under Section 361 of the PHS Act to the Commissioner of the FDA. See U.S. FDA Staff Manual Guide § 1410.10 (available at http://www.fda.gov/aboutfda/reportsmanualsforms/staffmanualguides/ucm080711.htm). It is through this rather complex series of events that the authority to promulgate regulations under Section 361 finally arrived with the FDA.

directly as from an infected person or animal or indirectly through the agency of an intermediate plant or animal host, vector, or the inanimate environment." 21 C.F.R. § 1240.3(b). Salmonellosis in this instance can fairly be characterized as an illness caused by infectious agents (*Salmonella*) transmitted from an infected animal (turtle) to a host (its human owner).[19]

We also find that Section 361 could fairly be read to authorize a ban on the sale of baby turtles under appropriate factual circumstances. Section 361 only specifies that the FDA may provide for "inspection, fumigation, disinfection, sanitation, pest extermination, [and] destruction of animals or articles found to be so infected or contaminated." 42 U.S.C. § 264(a). The ITFL suggests that we read this list of "powers" as an exhaustive one. However, the FDA's interpretation of this statute is entitled to wide deference. See Martinez, 519 F.3d at 542-43. Even absent such deference, the list directly precedes a "catch-all" grant of authority, allowing the Secretary (or the FDA Commissioner) to enact "other measures, as in his judgment may be necessary," in addition to the measures suggested in the list. 42 U.S.C. § 264(a). This phrase precludes interpretation of the list as exhaustive. Nonetheless, the list does not act as a limitation upon the types of regulations that may be enacted under Section 361. Instead, the list contains certain "measures" which the FDA may

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[19] The Defendants correctly argue that the application of two other legal principles warrants our acceptance of the FDA's interpretation of Section 361. First, when a statute contains an ambiguity, courts must defer to an agency's interpretation. Martinez v. Mukasey, 519 F.3d 532, 542-43 (5th Cir. 2008) (citing Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 845 (1984)). As long as the agency's interpretation of a statute is not "contrary to Congress's 'unambiguously expressed intent,'" the Court must afford it deference. Med. Ctr. Pharmacy v. Mukasey, 536 F.3d 383, 396 (5th Cir. 2008). The Court is aware of no such contrary intent, and the FDA's interpretation in this instance is at least facially reasonable. Second, because the PHS Act is remedial legislation, it is entitled to liberal construction. See Lifecare Hosps., Inc. v. Health Plus of La., Inc., 418 F.3d 436, 441 (5th Cir. 2005).

employ "[f]or purposes of carrying out and enforcing such regulations." Id.[20] The Turtle Ban is such a regulation, and therefore, is not limited by this clause.

In a further attempt to restrict the scope of Section 361, the ITFL argues that Section 361 does not grant the FDA authority to restrict "the sale or destruction of purely healthy turtles." (Doc. 58-1, p. 36). Again, because there is no express prohibition in the statute evidencing contrary congressional intent, the FDA's interpretation is entitled to deference. The ITFL again suggests that we read as exclusive the grant of authority to "provide for . . . destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings." 42 U.S.C. § 264(a). But the clause is not phrased as a limitation upon the *type* of regulation that may be promulgated by the FDA. Instead, Section 361 grants the FDA authority to enact "such regulations as in [its] judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases." Id. Again, we find the Turtle Ban to be a reasonable extrapolation from this statutory language under our deferential standard of review.[21]

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[20] It is important to note at this point that the Turtle Ban is not absolute. Rather, it contains exceptions for sales "for bona fide scientific, educational, or exhibitional purposes," sales "not in connection with a business," sales "intended for export only," and sales of "marine turtles excluded [by definition] from this regulation." 21 C.F.R. ?1 1240.62(e). In other words, the terms of the regulation target sales of baby turtles to small children who will use the turtles as pets, and who, in the FDA's expert judgment, are in the most danger of contracting *Salmonella* from the turtles. Considering these exceptions, the Turtle Ban is appropriately tailored to fit within the FDA's statutory authority under Section 361.

[21] Contrary to the ITFL's arguments, the fact that treatment may (or may not) render the turtles free of *Salmonella* does not alter this conclusion. Although the viability of the treatments referred to by the ITFL will be discussed more fully below, the FDA has not been convinced that turtles can be rendered entirely immune from *Salmonella* contamination. This means that there can be no certain conclusion that turtles can be made impervious to bacterial infection, and thus, not "dangerous" within the meaning of Section 361.

Finally, the Turtle Ban may encompass purely intrastate transactions under Section 361. In the preamble to the Turtle Ban, the FDA originally offered the following justification for banning intrastate sales of baby turtles:

> [T]he interstate spread of disease through *Salmonella*- and *Arizona*-contaminated turtles cannot be fully controlled without extending the ban to intrastate sales. All turtles present the same illness potential from *Salmonella* and *Arizona* organisms. Contaminated turtles may be purchased in one State for use as a pet in another. In addition, the existence of lawful business operations selling turtles within a State creates the possibility of unlawful interstate sales that are difficult or impossible to detect and stop.

40 Fed. Reg. at 22545. Clearly, the FDA contemplated that *intrastate* commerce in baby turtles would significantly impact *interstate* commerce, a conclusion which is perfectly logical in this instance. Although Section 361, by its terms, provides for the regulation of foreign or interstate transactions, the connection between intrastate and interstate commerce is immutable. In the context of Congress's constitutional jurisdiction under the interstate commerce clause, it is well-settled that intrastate activities "that have a substantial effect on interstate commerce" may be regulated. United States v. Bird, 401 F.3d 633, 635 (5th Cir. 2005). Therefore, the ITFL's argument on this point is without merit.

Giving deference to the FDA's interpretation of 42 U.S.C. § 264(a), as we must, we find that the Turtle Ban was neither originally enacted, nor continued as of May 31, 2006, "in excess of [the FDA's] statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C). Therefore, the ITFL's motion for summary judgment will be DENIED as to this argument.

5. *Arbitrary and Capricious*

a. Legal Standards

Pursuant to the APA, the Court is also authorized to "compel agency action unlawfully withheld or unreasonably delayed," or to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(1), (2)(A). Our review under this standard, however, is notably constrained:

> Under the "arbitrary and capricious" standard the scope of review is a narrow one. A reviewing court must "consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment. . . . Although this inquiry into the facts is to be searching and careful, the ultimate standard of review is a narrow one. The court is not empowered to substitute its judgment for that of the agency."

Miranda v. Nat'l Transp. Safety Bd., 866 F.2d 805, 807 (5th Cir. 1989) (quoting Bowman Transp., Inc. v. Ark.-Best Freight Sys., Inc., 419 U.S. 281, 285 (1974)). As long as an agency's judgment conforms to "minimum standards of rationality," the agency's decision should be upheld. Public Citizen, Inc. v. EPA, 343 F.3d 449, 455 (5th Cir. 2003). Moreover, the agency's "interpretations of its regulations are entitled to substantial deference and are given 'controlling weight' unless 'plainly erroneous or inconsistent with the regulation.'" Id. at 455-56 (quoting Thomas Jefferson Univ. v. Shalala, 512 U.S. 504, 512 (1994)).

Although our standard of review is deferential, the Court "may not defer to an agency decision that 'is without substantial basis in fact.'" La. Envtl. Action Network v. EPA, 382 F.3d 575, 582 (5th Cir. 2004) (quoting Fed. Power Comm'n v. Fla. Power &

Light Co., 404 U.S. 453, 463 (1972)). Thus, an agency decision may be deemed arbitrary and capricious

> if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Id. (quoting Tex. Oil & Gas Ass'n v. EPA, 161 F.3d 923, 934 (5th Cir. 1998)). In making this determination, we must begin by affording the FDA's decision a "'presumption of regularity.'" Pension Ben. Guar. Corp. v. Wilson N. Jones Memorial Hosp., 374 F.3d 362, 366 (5th Cir. 2004) (quoting United States v. Garner, 767 F.2d 104, 116 (5th Cir. 1985)). Moreover, we must "limit our review to whether the agency articulated a rational connection between the facts found and the decision made, and it is well-settled that an agency's action must be upheld, if at all, on the basis articulated by the agency itself." Hayward v. U.S. Dep't of Labor, 536 F.3d 376, 380 (5th Cir. 2008) (internal citations and quotations omitted).

There is some dispute between the parties related to the applicability of the Fifth Circuit's holding in Corrosion Proof Fittings v. EPA, 947 F.2d 1201 (5th Cir. 1991). In that case, the Fifth Circuit considered a challenge to an EPA regulation passed under the Toxic Substances Control Act ("TSCA") "prohibiting the manufacture, importation, processing, and distribution in commerce of most asbestos-containing products." Id. at 1207-08. The court noted that, as a general matter, "we give all agency rules a presumption of validity, and it is up to the challenger to any rule to show that the agency action is invalid." See id. at 1214.

However, under the specific provisions of the TSCA, which include "substantial evidence" and "least burdensome regulation" provisions different from general APA, "[t]he burden remains on the EPA . . . to justify that the products it bans present an unreasonable risk, no matter how regulated." See id.

Although the ITFL would have this Court rule that all agencies that have totally banned a product are subject to the Corrosion Proof Fittings standard, the court's holding was limited to the TSCA context. That statute realigns the burdens of proof prescribed by the APA. Moreover, the Seventh Circuit's opinion in American Dental Ass'n v. Martin does not alter that conclusion. 984 F.2d 823 (7th Cir. 1993). One member of the circuit panel in Martin opined that "the holding of Corrosion Proof Fittings offers guidance as to how all federal agencies should regulate. Id. at 838 n.11. However, that judge did not join the majority opinion, but rather was concurring in part and dissenting in part. Even if the firm position in the Seventh Circuit was that the Corrosion Proof Fittings reasoning is applicable in all cases considering a regulatory ban, no opinion binding upon this Court has held the same. Thus, the normal standards of proof and presumptions apply to our determination in this case.[22]

b. The FDA's May 31, 2006 Decision

Once again, the FDA decided in its letter response that the ITFL's "submission . . . does not demonstrate that *Salmonella*-free turtles can be consistently produced

[22] The ITFL asserts that Section 7(c) of the APA imposes upon the FDA the burden of proof in this case. That section states: "[e]xcept as otherwise provided by statute, the proponent of a rule or order has the burden of proof." 5 U.S.C. § 556(d). However, by its terms, this provision clearly applies "to hearings required by section 553 or 554 of this title

and that, if *Salmonella*-free turtles are produced, they will not be recontaminated with *Salmonella sp.* after shipment." (Doc. 58-4, Exh. 18). We find that the FDA's decision, at least at that point, was not arbitrary and capricious. That determination tosses us into the latter portion of the regulation, addressing "petitions. 21 C.F.R. § 1240.62(e). In that subsection, it is provided that one may petition for a change in the regulation based upon "reasonable grounds." Id.

As observed above, what is meant by the term "reasonable grounds" is not made clear in the text of the regulation. But as the Defendants point out, the preamble to the originally enacted Turtle Ban includes a response to a comment submitted to the FDA shedding light on this issue. Specifically, the preamble provided that "the Commissioner will at any time in the future consider evidence presented to him which demonstrates that *Salmonella*- and *Arizona*-free turtles can be produced and that sufficient safeguards exist to prevent a public health hazard through recontamination of turtles after shipment." 40 Fed. Reg. at 2544. Another response to a comment stated that "[i]f in fact a significantly improved certification scheme is developed or a *Salmonella*- and *Arizona*-free turtle is produced by the turtle industry, the Commissioner, based on the data presented, by interested persons, will consider changing the restrictions on the sale and distribution of turtles." Id. at 22545.[23]

In short, the preamble indicates that the FDA would consider lifting or

[23] Other language in the preamble contained similar indications. See 40 Fed. Reg. at 2244 ("[T]he entire matter should be reconsidered if research demonstrates means whereby turtles could be kept *Salmonella*- and *Arizona*-free.").

amending the Turtle Ban upon submission of proof of: (1) a significantly improved certification scheme, or (2) a method of producing turtles that are both free of and immune to contamination with *Salmonella*.[24] This language is consistent with subsequent correspondence issued by the FDA.[25] Ultimately, the FDA concluded that, while the ITFL's research was scientifically sound, none of the studies submitted by the ITFL met these standards.

In one study, which we will refer to as the "Baquacil study," the researchers' goal was to eliminate the presence of *Salmonella* in the habitat of RES turtles. The turtles were kept in dechlorinated water, with two test groups receiving treatment with Baquacil, and the third group receiving no such treatment. In evaluating the Baquacil study, the FDA noted that "[t]he finding of *Salmonella*-positive samples in the intestinal tracts of RES [red-eared slider] turtles in the three treatment groups (70% for the 25 ppm group; 75% for the 50 ppm group; and 80% for the control group) demonstrates that turtles harbor *Salmonella* even after water treatment with Baquacil." (Doc. 58-4, Exh. 18, p. 2). Moreover, the study did not evaluate the possibilities of *Salmonella* recolonization during or after shipment. Overall, the water

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[24] An agency's interpretations of its own regulations, such as the FDA's interpretation of the Turtle Ban, are entitled to "'considerable legal leeway.'" Ovalles v. Holder, 577 F.3d 288, 291-92 (5th Cir. 2009) (quoting Navarro-Miranda v. Ashcroft, 330 F.3d 672, 675 (5th Cir. 2003)). "However, '[w]hile an agency interpretation of a regulation is entitled to due deference, the interpretation must rationally flow from the language of the regulation.'" Ovalles, 577 F.3d at 292 (quoting Navarro-Miranda, 330 F.3d at 675). In this instance, we find that the FDA's interpretation of the Turtle Ban is reasonable.

[25] In a letter responding to a citizen's concerns regarding the Turtle Ban, the FDA emphasized the "need for adequate documentation of the absence of *Salmonella* in pet turtles, including . . .[e]limination of *Salmonella* from the hatchlings . . . [d]emonstration that resistance to the treatment does not occur . . . [and] [d]emonstration that the turtles do not become re-colonized by *Salmonella*." Doc. 58-3, Exh. 5).

samples treated with Baquacil were less likely to contain (although not always free of) *Salmonella*. However, the instance of *Salmonella* in the turtles' intestinal tracts was substantially similar whether their habitats were treated with Baquacil or not. This indicated that the treatment, in Dr. Mitchell's words, had "no effect on colonization of *Salmonella* in these animals." (Doc. 5, Tab 3, p. 2). Thus, while the Baquacil treatment was at least moderately effective in eliminating *Salmonella* in the turtles' habitats, the FDA determined it appeared to have no effect on *Salmonella* colonization in the turtles themselves.

Another study involving the treatment of water columns with a substance called Vantocil was likewise insufficient ("Vantocil study"). The Vantocil study evaluated the effects of treatment with Vantocil as a means of eliminating *Salmonella* contamination in the water of RES turtles during transportation, as well as in the intestines of the turtles. The turtles were divided into three groups, placed in boxes to simulate shipping conditions, and shipped to researchers by truck. Results showed that Vantocil treatment effectively reduced contamination of the turtles' habitat during transportation, but did not eliminate *Salmonella* from the turtles' intestinal tracts. According to the FDA, "although this study indicates that [the treating substance] may help prevent *Salmonella* in the water columns of turtles being transmitted, the FDA further determined it does not demonstrate that [the treating substance] eliminates *Salmonella* from turtles." (Doc. 58-4, Exh. 18, p. 3).

In the third and final study submitted by the ITFL, researchers evaluated a hybrid approach combining methods of soaking turtle eggs in a Clorox solution and

treating the eggs with antibiotics or antimicrobial substances, such as Baquacil ("Clorox and Baquacil study"). Despite some success, each of the test groups nonetheless yielded at least some *Salmonella*-positive results. While the Clorox and Baquacil study indicated that the three methods examined all "reduce[d] the prevalence of *Salmonella* on/in RES eggs and hatchlings . . . this study does not demonstrate that turtles can be reliably rendered *Salmonella*-free, or that they will not be recolonized by *Salmonella* after transport off-farm," according to the FDA. (Doc. 58-4, Exh. 18, p. 3).

In sum, the FDA concluded that, "[a]lthough the studies [the ITFL] submitted appear to be well designed, they do not demonstrate that turtles can consistently and reliably be rendered *Salmonella*-free, or that when rendered *Salmonella*-free, they will not be recolonized by *Salmonella*." (Doc. 58-4, Exh. 18, p. 4). The Court has carefully evaluated the studies submitted by the ITFL with its petition. In doing so, the Court has borne in mind the settled principle that, "[i]n reviewing technical agency decisions . . . '[w]e must look at the decision not as a chemist, biologist, or statistician that we are qualified neither by training nor experience to be, but as a reviewing court exercising our narrowly defined duty of holding agencies to certain minimal standards of rationality.'" Hayward, 536 F.3d at 380 (quoting Gulf Restoration Network v. U.S. Dep't of Transp., 452 F.3d 362, 368 (5th Cir. 2006)). Ultimately, we are unable to conclude that the FDA's decision to deny the ITFL's petition was arbitrary and capricious based upon what *was* in the record at that point.

Again, the Court is obligated to defer to an agency's interpretation of its own

regulations. In this case, the FDA's interpretation of the Turtle Ban mandates that a petition would have to include proof that a turtle can be produced which is free of and immune to re-contamination by *Salmonella*. The studies submitted by the ITFL did not satisfy that standard. Tellingly, the ITFL does not presently argue to the contrary. Rather, the three methodologies summarized in the studies attached to the ITFL's petition only reduce, or temporarily eliminate, *Salmonella* in the turtles' habitats or in the turtles themselves. Put another way, none of the treatment regimens proposed by the ITFL can yield a turtle impervious to *Salmonella* contamination, which is the mark demanded by the FDA.

In view of our ruling on the supplementation of the administrative record, judging from the evidence presently before the Court, and under the FDA's interpretation of the Turtle Ban, the FDA's decision to deny the ITFL's petition was not arbitrary or capricious. Therefore, as to this particular issue, the ITFL's motion for summary judgment will be DENIED IN PART, and the Defendants' motion for summary judgment will be GRANTED IN PART.

c. Other Issues

Our conclusion that the FDA's properly rejected the three methodologies presented in the ITFL's petition under its own interpretation of the Turtle Ban does not end the Court's inquiry in this case. A number of other arguments remain which bear further explanation.

First, the ITFL argues that the Turtle Ban constitutes disparate treatment, because the FDA does not presently prohibit the sale of any other pet, and does not

regulate food products as stringently. In response, the FDA concedes that "many other products may be contaminated with microorganisms, including *Salmonella*." (Doc. 58-4, Exh. 18). However, the has FDA emphasized that small children are the "at-risk population handling small pet turtles." (Doc. 58-4, Exh. 18). This, in the FDA's view, justifies the exacting, and perhaps "discriminatory," emphasis upon the pet turtle industry. On the record before the Court, we disagree.

The ITFL's arguments regarding other food products and pets were fairly raised in the petition, as determined above. In truth, the FDA's minimal response provides the ITFL, and this Court, with little insight into the unique threat posed to children by small turtles. Although it is intuitive that children may fail to observe standards of hygiene which would otherwise prevent *Salmonella* contamination, other aspects of the FDA's reasoning are not abundantly clear. For instance, the FDA fails to explain, even in broad terms, why the ITFL's contentions that other pets and food products could also present a risk of contamination to children do not have traction.[26] Moreover, the FDA nowhere articulates why other pets attractive to small children and potentially carrying *Salmonella* do not pose similar risks, and are not regulated or banned. Likewise, nothing is addressed as to why the issue of sale of these turtles could not be addressed with regulations and required warnings rather

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[26] As the ITFL points out, an agency decision may be found arbitrary and capricious because it constitutes disparate treatment of similarly situated entities. ("[W]e must insist that the FDA apply its scientific conclusions evenhandedly and that it not 'grant to one person the right to do that which it denies to another similarly situated'. . . . Deference to administrative discretion or expertise is not a license to a regulatory agency to treat like cases differently."). See, e.g., United States v. Diapulse Corp. of Am., 748 F.2d 56, 62 (2d Cir. 1984). Moreover, "failing to give a reasonable explanation for how [an agency] reached its decision" may make an agency's decision arbitrary and capricious under the APA. Transitional Learning Community at Galveston, Inc. v. U.S. Office of Personnel Management, 220 F.3d 427, 430 n.2 (5th Cir. 2000).

than a total ban.[27] Because these questions were raised in the ITFL's petition, we find the FDA's failure to adequately address them to be arbitrary and capricious.[28]

Moreover, there were a number of issues that were not raised by the ITFL in its petition to the FDA. Those issues included: (1) that larger turtles pose the same risks of spreading *Salmonella* as small turtles, making the Turtle Ban arbitrary and capricious; and (2) the possible impacts of "scientific advances" such as antibacterial soap and antibiotic treatments upon the Turtle Ban. As noted above, the FDA has had no opportunity thus far to evaluate these questions, and has seen no evidence upon which to conduct such an evaluation. Therefore, these issues remain in dispute.

The ITFL also argues that the Turtle Ban constructs an impossible standard for those seeking to lift or amend the ban.[29] Phrased differently, the ITFL poses the question of whether it is scientifically feasible to produce either (1) a more effective certification process, or (2) turtles which are free of and immune to colonization by *Salmonella*. This question is critical because courts are only required to defer to agency interpretations which are "reasonable." See, e.g., Public Citizen, Inc., 343

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[27] This issue is raised most explicitly in Dr. Mitchell's letter, which was attached to the ITFL's petition. In the letter, Dr. Mitchell states that the FDA "currently provides . . . other industries and consumers guidelines as to different methods they can use to minimize transmission of pathogenic organisms. Why can't the FDA do the same for the aquatic chelonian industry?" (Doc. 5-3, p. 6). That question remains unanswered.

[28] We are aware that "[c]ourts will 'uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned.'" Hayward, 536 F.3d at 380 (quoting Nat'l Ass'n of Home Builders v. Defenders of Wildlife, 551 U.S. 644, 658 (2007)). However, we find it difficult to discern the FDA's reasoning for banning entirely the sale of turtles of a particular size while conceding that other products may conceivably present *Salmonella* risks. Some of those products, including certain types of pets, must also be attractive and accessible to small children. The lingering presence of these questions compels our decision herein.

[29] In particular, the ITFL noted that some federal researchers have opined that it is not possible to produce a reptile that is "*Salmonella*-free." (Doc. 58-1, p. 15).

F.3d at 455. Our inquiry may extend to whether "the agency's judgment conforms to minimum standards of rationality." See La. Envtl. Action Network, 382 F.3d at 582. The ITFL's essential position is that the Turtle Ban, as it has been interpreted by the FDA, presents insurmountable scientific obstacles that neither conform to rational standards, nor compare to regulations promulgated in similar industries.

At least on the surface, we share the ITFL's concerns, without passing any judgment upon the scientific viability of the Turtle Ban. Given its age, strictness, and selectivity, the time has come to reevaluate the basis of the Turtle Ban in the modern era. The Court is not the proper forum for reevaluation at this time, however. It is suggested in the administrative record by the ITFL that the Turtle Ban's standards are impossible to satisfy and that such may violate the boundaries of the FDA's power.[30] But in fairness to the FDA, the argument was not articulated in any detail. Thus, we consider it an issue which the ITFL failed to exhaust, and we will allow the FDA the first opportunity to address it.

D. Proper Remedy

The final question remaining before the Court is what remedy would be appropriate under the circumstances of this case. The ITFL seeks vacatur of the Turtle Ban in its entirety. Given our holdings, however, it is clear that this remedy is not appropriate, at least not at this time, for this Court. Questions remain which require the expertise and resources of the FDA. As delineated above, these remaining questions roughly fall into two categories: issues upon which the FDA's

[30] Specifically, in a letter attached to the ITFL's petition, Dr. Mitchell contends that the FDA has "saddled a group of individuals with an unobtainable set of guidelines." (Doc. 5-3, Tab 2, p. 7).

determination was, for one reason or another, arbitrary and capricious, and issues which were not fairly or adequately presented to the FDA for initial determination.

As to the first category, precedent in this circuit makes clear that the proper remedy is remand to the administrative agency, rather than vacatur:

> Where, as here, a court determines that an agency has acted arbitrarily or capriciously, the APA permits the court to hold unlawful and set aside that action. 5 U.S.C. § 706(2). As a general rule, when an agency decision is not sustainable on the basis of the administrative record, then the matter should be remanded to [the agency] for further consideration. Only in rare circumstances is remand for agency reconsideration not the appropriate solution.

O'Reilly v. U.S. Army Corps of Eng'rs, 477 F.3d 225, 238-39 (5th Cir. 2007) (internal citations and quotations omitted). Moreover, "[c]ourts have explained that 'remand is generally appropriate when there is at least a serious possibility that the [agency] will be able to substantiate its decision given an opportunity to do so, and when vacating would be 'disruptive.'" Central and South West Services, Inc. v. EPA, 220 F.3d 683, 692 (5th Cir. 2000). Because this case presents no unusual circumstances which may justify vacatur of the Turtle Ban at this point, and because such a vacatur would be disruptive to the administrative and scientific process, these issues will be remanded to the FDA.

As to the second category, "remand is normally appropriate where a district court arrives at an issue that an agency has not yet evaluated.'" BizCapital Bus. & Indus. Dev. Corp. v. Comptroller of the Currency of the U.S., 467 F.3d 871, 872 (5th Cir. 2006). Moreover, remand is one of the remedies explicitly contemplated by the FDA's procedural regulations as well. See 21 C.F.R. § 10.25(b) ("FDA . . . will request a court

to dismiss, or to hold in abeyance its determination of or refer to the agency for administrative determination, any issue which has not previously been determined by the agency. . . ."). Therefore, the issues which the FDA has yet to make a determination upon will likewise be remanded.

III. Conclusion

The Court appreciates the genuine efforts of both parties to protect a valuable set of interests. The ITFL seeks to reinvigorate a domestic business and to provide popular, and safe, pets to a likely receptive market of citizens. The Defendants, however, are concerned with safeguarding those citizens, and in particular, small children, from the risk of unwittingly contracting a dangerous and potentially deadly bacteria. However, this case presents issues of rights under law, not of appreciation or sympathy.

As we understand the science and society of 1975, the regulation we have reaffirmed was not arbitrary and capricious when it was implemented. However, the evidence before the Court indicates that both the science and our society have changed dramatically. Because the administrative record does not include scientific evidence to support all of the arguments set forth in the ITFL's petition (or some of the new arguments presented to the Court), and because no public comment or other hearing was allowed at the administrative level, the ITFL submitted evidence to this Court that was not presented to the FDA. These shortcomings further evidence the need for additional proceedings at the administrative level. We sit as a reviewing court, and not a trial court, in this case. Therefore, as specified above, the Court will

remand this matter to the FDA for further proceedings consistent with this ruling.

SIGNED on this 24th day of March, 2010 at Alexandria, Louisiana.

DEE D. DRELL
UNITED STATES DISTRICT JUDGE

21 C.F.R. § 1240.62

Code of Federal Regulations
Title 21. Food and Drugs
Chapter I. Food and Drug Administration, Department of Health and Human Services
Subchapter L. Regulations Under Certain Other Acts Administered by the Food and Drug Administration
Part 1240. Control of Communicable Diseases
Subpart D. Specific Administrative Decisions Regarding Interstate Shipments
1240.62 Turtles intrastate and interstate requirements.

(a) Definition. As used in this section the term "turtles" includes all animals commonly known as turtles, tortoises, terrapins, and all other animals of the order Testudinata, class Reptilia, except marine species (families Dermachelidae and Chelonidae).

(b) Sales; general prohibition. Except as otherwise provided in this section, viable turtle eggs and live turtles with a carapace length of less than 4 inches shall not be sold, held for sale, or offered for any other type of commercial or public distribution.

(c) Destruction of turtles or turtle eggs; criminal penalties.

(1) Any viable turtle eggs or live turtles with a carapace length of less than 4 inches which are held for sale or offered for any other type of commercial or public distribution shall be subject to destruction in a humane manner by or under the supervision of an officer or employee of the Food and Drug Administration in accordance with the following procedures:

(i) Any District Office of the Food and Drug Administration, upon detecting viable turtle eggs or live turtles with a carapace length of less than 4 inches which are held for sale or offered for any other type of commercial or public distribution, shall serve upon the person in whose possession such turtles or turtle eggs are found a written demand that such turtles or turtle eggs be destroyed in a humane manner under the supervision of said District Office, within 10 working days from the date of promulgation of the demand. The demand shall recite with particularity the facts which justify the demand. After service of the demand, the person in possession of the turtles or turtle eggs shall not sell, distribute, or otherwise dispose of any of the turtles or turtle eggs except to destroy them under the supervision of the District Office, unless and until the Director of the Center for Veterinary Medicine withdraws the demand for destruction after an appeal pursuant to paragraph (c)(1)(ii) of this section.

(ii) The person on whom the demand for destruction is served may either comply with the demand or, within 10 working days from the date of its promulgation, appeal the

demand for destruction to the Director of the Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. The demand for destruction may also be appealed within the same period of 10 working days by any other person having a pecuniary interest in such turtles or turtle eggs. In the event of such an appeal, the Center Director shall provide an opportunity for hearing by written notice to the appellant(s) specifying a time and place for the hearing, to be held within 14 days from the date of the notice but not within less than 7 days unless by agreement with the appellant(s).

(iii) Appearance by any appellant at the hearing may be by mail or in person, with or without counsel. The hearing shall be conducted by the Center Director or his designee, and a written summary of the proceedings shall be prepared by the person presiding. Any appellant shall have the right to hear and to question the evidence on which the demand for destruction is based, including the right to cross-examine witnesses, and he may present oral or written evidence in response to the demand.

(iv) If, based on the evidence presented at the hearing, the Center Director finds that the turtles or turtle eggs were held for sale or offered for any other type of commercial or public distribution in violation of this section, he shall affirm the demand that they be destroyed under the supervision of an officer or employee of the Food and Drug Administration; otherwise, the Center Director shall issue a written notice that the prior demand by the District Office is withdrawn. If the Center Director affirms the demand for destruction he shall order that the destruction be accomplished in a humane manner within 10 working days from the date of the promulgation of his decision. The Center Director's decision shall be accompanied by a statement of the reasons for the decision. The decision of the Center Director shall constitute final agency action, reviewable in the courts.

(v) If there is no appeal to the Director of the Center for Veterinary Medicine from the demand by the Food and Drug Administration District Office and the person in possession of the turtles or turtle eggs fails to destroy them within 10 working days, or if the demand is affirmed by the Director of the Center for Veterinary Medicine after an appeal and the person in possession of the turtles or turtle eggs fails to destroy them within 10 working days, the District Office shall designate an officer or employee to destroy the turtles or turtle eggs. It shall be unlawful to prevent or to attempt to prevent such destruction of turtles or turtle eggs by the officer or employee designated by the District Office. Such destruction will be stayed if so ordered by a court pursuant to an action for review in the courts as provided in paragraph (c)(1)(iv) of this section.

(2) Any person who violates any provision of this section, including but not limited to any person who sells, offers for sale, or offers for any other type of commercial or public distribution viable turtle eggs or live turtles with a carapace length of less than 4 inches, or who refuses to comply with a valid final demand for destruction of turtles or turtle eggs (either an unappealed demand by an FDA District Office or a

demand which has been affirmed by the Director of the Center for Veterinary Medicine pursuant to appeal), or who fails to comply with the requirement in such a demand that the manner of destruction be humane, shall be subject to a fine of not more than $1,000 or imprisonment for not more than 1 year, or both, for each violation, in accordance with section 368 of the Public Health Service Act (42 U.S.C. 271).

(d) Exceptions. The provisions of this section are not applicable to:

(1) The sale, holding for sale, and distribution of live turtles and viable turtle eggs for bona fide scientific, educational, or exhibitional purposes, other than use as pets.

(2) The sale, holding for sale, and distribution of live turtles and viable turtle eggs not in connection with a business.

(3) The sale, holding for sale, and distribution of live turtles and viable turtle eggs intended for export only, provided that the outside of the shipping package is conspicuously labeled "For Export Only."

(4) Marine turtles excluded from this regulation under the provisions of paragraph (a) of this section and eggs of such turtles.

(e) Petitions. The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may publish a proposal to amend this regulation. Any such petition shall include an adequate factual basis to support the petition, and will be published for comment if it contains reasonable grounds for the proposed regulation. A petition requesting such a regulation, which would amend this regulation, shall be submitted to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

[40 FR 22545, May 23, 1975, as amended at 46 FR 8461, Jan. 27, 1981; 48 FR 11431, Mar. 18, 1983; 54 FR 24900, June 12, 1989; 59 FR 14366, March 28, 1994; 70 FR 48073, Aug. 16, 2005]

SOURCE: 40 FR 5620, Feb. 6, 1975; 52 FR 29514, Aug. 10, 1987; 54 FR 24900, June 12, 1989; 54 FR 39642, Sept. 27, 1989; 62 FR 51521, Oct. 1, 1997, unless otherwise noted.

AUTHORITY: 42 U.S.C. 216, 243, 264, 271.

APPENDIX A